REMARKS

Claims 1-9, 11, 12, and 14 are currently pending in this application. Claims 1, 5-9, 11, and 14 have been amended. Paragraphs [0047] and [0068] of the specification have been amended. These amendments introduce no new matter into the application.

Election/Restriction Requirement

With respect to the first species election of January 15, 2008, and the February 27, 2008 telephone conversation with the Examiner, Applicants affirm the election of polyoxypropylene polyoxyethylene condensates as the solutizer, and the election of macrolide antibiotics as the effective agent.

Objections to the Specification

The Action objected to the specification for the recitation of "references are given in Fig. 1." Paragraph [0068] has been amended to instead state "[w]ith reference to Fig. 1," to clarify that this section of the description refers to Fig. 1.

The Action further objected to the specification for the use of the term "explosives," to describe starches, cross-linked polyvinyl pyrrolidon, algine acid, and

salts therefrom. Paragraph [0047] has been amended to replace the term "explosives" with "disintegrants."

Claim Objections

The Action objected to claim 5 for the use of the term "analgetics." Claim 5 has been amended to replace this term with "analgesics."

Claim Rejections - 35 USC §112

The Action rejected claims 1-9, 11, 12, and 14 under 35 U.S.C. §112, first and second paragraphs for the recitation "hard to dissolve" when describing the effective agents. Each of the claims reciting this limitation has been amended to remove this language.

The Action rejected claim 5 under 35 U.S.C. §112, second paragraph for the use of the term "comprising" within the Markush group. Claim 5 has been amended to remove this recitation.

The Action went on to reject claim 7 under 35 U.S.C. §112, second paragraph for indefiniteness with respect to the requirements that the fluidized bed be "empty" at the beginning of the process, and that the starting seeds for pelletizing be formed in the absence another "inert material." Claim 7 has been amended replace the

term "empty" with "free from core-forming substances that act as seeds," and "inert material" with "core forming inert substances."

The Action rejected claim 8 under 35 U.S.C. §112, second paragraph as indefinite for the recitations "several respective effective agents," and "a respective mixture of effective agents," holding the difference between these claim elements to be unclear. Claim 8 has been amended to replace this language with "at least one micronized effective agent."

The Action further rejected claim 8 under 35 U.S.C. §112, second paragraph for being unclear as to whether either or both of deaeration and homogenization are required throughout the step recited in the second paragraph of the claim. The second paragraph of claim 8 has been amended to clarify that throughout this step, a single process of either or both deaeration or homogenization takes place. The amendment makes clear that the recitations "a jet stream mixer for at least one of homogenizing and deaerating," and "the suspending taking place under at least one of deaeration and homogenization," refer to the same process of deaerating and/or homogenizing the dispersion.

The Action also rejected claim 8 under 35 U.S.C. §112, second paragraph for indefiniteness with respect to the location of the final step of mixing and deaerating the products of the second and third paragraphs. The second and fourth paragraphs of claim 8 have been amended to clarify that the homogenous

suspension of the second paragraph takes place by a "dispersion device and a by a jet stream mixer," and that in the step of the fourth paragraph the homogenous solution of the third paragraph is "introduced and mixed with the homogenous suspension," of the second paragraph, "the mixture and the deaeration being simultaneously carried out by the jet stream mixer," also used for deaeration and homogenization of the suspension of the second paragraph.

Finally, the Action rejected claim 8 under 35 U.S.C. §112, second paragraph for the recitation of "advantageously" preceding the requirement of "using powder wetting or dispersing devices." The claim has been amended to remove the term "advantageously" to make clear that the use of powder wetting or dispersing devices is required."

Double Patenting Rejection

The Action provisionally rejected claims 1, 5, and 6 under the judicially created doctrine of obviousness-type double patenting over copending Application No. 11/876,214 in view of Schutte et al. (U.S. 6,159,252).

The '214 Application teaches a process for making coated pellets from granulates of marcolide antibiotics (effective agents). As recognized by the Action, the '214 Application fails to teach a method of forming the granulates. Schutte et

al. teach a process for forming granular solids from liquids using fluidized bed spray granulation, but fails to teach or suggest every limitation of Applicants' claim.

With respect to claim 1, neither for the references suggest combining a suspension of the micronized effective agent with a solution of dissolved adjuvants. While Schutte et al. teach that dissolved or dispersed solids can be used to produce granules, it fails to teach the particular configurations of the components of Applicants' claims. Claim 1 requires the step of "producing the micropellets from liquid dispersions of solid micronized particles in the presence of functional adjuvants," and "the functional adjuvants...being provided in a dissolved or dispersed form." Schutte et al never suggests such steps.

Claims 5 and 6 depend from claim 1 and should be patentable for at least the reasons discussed above.

Claim Rejections - 35 USC §102

The Action rejected claims 1, 2, 5, 8, 9, 11, 12 and 14 under 35 U.S.C. §102(b) as anticipated by Upadhyay (6,264,983).

Upadhyay fails to disclose the use of a liquid dispersion or suspension of effective agents to produce micropellets. As recited in the independent claims: "producing the micropellets from liquid dispersions of solid micronized particles," (claim 1), and "a homogenous suspension of at least one solid micronized effective

agent is produced in water," (claim 8). As recognized by the Action, Upadhyay teaches a method in which "acetaminophen and a dispersion of the adjuvant particles in air are prepared." See Action at p. 11.

Applicants' step of preparing a liquid dispersion or suspension of the effective agent permits deaeration and mixing to be carried out together so that the adjuvants can be directly added to the dispersion without the formation of undesired foam. See Substitute Specification at paragraph [0034].

Additionally, claim 8 specifically requires "mixing and deaerating the homogenous suspension of the firsts step and the homogenous solution of the other separate step." Upadhyay's process takes place in the presence of air and includes no steps directed towards its removal. Claim 8 is therefore further patentable because Upadhyay fails to teach the step of deaerating.

The Action rejected claims 1-3, 8, 11, 12, and 14 under 35 U.S.C. §102(b) as anticipated by Appel et al. (EP 1027887).

Appel et al. fail to disclose an intermediate step of forming a liquid dispersion or suspension of solid particles of the effective agent. As recited in the independent claims: "producing the micropellets from liquid dispersions of solid micronized particles of the effective agents," (claim 1), and "a homogenous suspension of the at least one micronized effective agent is produced in water," (claim 8). This language requires that the micronized particles be suspended in a solid state in the liquid.

While the final product of Appel et al. is a dispersion, the reference fails to teach producing a dispersion of the effective agent as an intermediate step for producing an end product suitable for administration.

According to the method of Appel et al., the effective agent must be dissolved. As stated at paragraph [0042], "[a] particularly preferred method of forming the dispersion is by dissolving the drug and the matrix polymer in a common solvent." This distinction is even recognized in the Action, which states "the polymer and the drug must be dissolved in a common solvent to form the dispersion." See Action at p.15.

Claim Rejections - 35 USC §103

The Action rejected claims 1, 5, 6, and 11 under 35 U.S.C. § 103(a) as obvious over Appel et al., claim 4 under 35 U.S.C. §103(a) as obvious over Appel et al., in view of Clancy et al. (WO 97/02017), and claims 1, 7, and 9 under 35 U.S.C. §103(a) as obvious over Appel et al. in view of Glad (WO 01/03809).

As discussed above, Appel et al. fail to teach forming a liquid dispersion or suspension of the effective agent. None of the secondary reference remedy this deficiency. Each of these claims should therefore be patentable for at least those reasons discussed above with respect to the claim rejections under 35 U.S.C. §102(b).

Conclusion

If the Examiner believes that any additional minor formal matters need to be addressed in order to place this application in condition for allowance, or that a telephone interview will help to materially advance the prosecution of this application, the Examiner is invited to contact the undersigned by telephone at the Examiner's convenience.

In view of the foregoing amendment and remarks, Applicants respectfully submit that the present application, including claims 1-9, 11, 12, and 14, is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

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